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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In Re National Phase Patent Application of: J. Michael Fitzpatrick, *et al.* | | | |
| Conf. No.: | Not Yet Assigned | Group Art Unit: | Not Yet Assigned |
| International Appln. No.: | PCT/US04/0014141 | Examiner: | Not Yet Assigned |
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| U.S. Appln. No.: | Not Yet Assigned | | |
| U.S. Filing Date: | | | |
| Title: | Fiducial Marker Holder System for Surgery | | |

**PETITION TO MAKE SPECIAL FOR NEW APPLICATION UNDER MPEP § 708.02, VIII**

RECEIVED
17 JUL 2006
Legal Staff
International Division

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313

ATTENTION: Group Director, Group 3700

**1. Petition**

Applicants hereby petition to make special the above-identified new application, which has not received any examination by the Examiner.

## 2. Claims

All currently pending claims in the application (i.e., claims 1-19) are directed to a single invention. If the Office determines that all of the claims presented are not obviously directed to a single invention, then Applicants will make an election without traverse as a prerequisite to the grant of special status.

## 3. Search

A search has been made by the International Searching Authority in corresponding International Application No. PCT/US04/0014141 (PCT publication WO 2004/100767 A3 attached hereto).

IPC (7): AGIB 1900

US Class 606, subclass 130

The U.S. Patent and Trademark Office (USPTO) was the selected international Receiving Office (RO) for the international application. Thus, the RO was functioning in the capacity of an international (foreign) office to search the international application.

MPEP § 708.02 VIII, (C) recites:

> (C) Submits a statement(s) that a pre-examination search was made, listing the field of search by class and subclass, publication, Chemical Abstracts, foreign patents, etc. A search made by a foreign patent office satisfies this requirement.... [underline emphasis added].

Accordingly, since the RO was functioning in the capacity of an international (foreign) office to search the international application, the international search constitutes a pre-examination search as set forth in MPEP § 708.02 VIII, (C).

The Authorized Officer cited one "X" reference, U.S. Patent No. 6,096,048 A ("Howard III, *et al.*," hereinafter, "Howard '048").

Additionally, Applicants also cited references known to them on an Information Disclosure Statement filed herewith.

## 4. Copy of References

Copies of the references deemed most closely related to the subject matter encompassed by the claims at the time the application was filed were submitted with an Information Disclosure Statement (IDS) filed herewith. The references are listed on a Form PTO/SB/08A filed concurrently with the IDS papers. Both sets of references are discussed below.

## 5. Detailed Discussion of the References

There is submitted herewith a detailed discussion of the references from the IDS's, which discussion particularly points out how the claimed subject matter is distinguishable over the references.

The claimed subject matter is patentably distinguishable over the references for at least the following reasons:

None of the references discussed below disclose or suggest a marker attachment device disposed at a distal end of the second arm of an open-ended frame, wherein the marker attachment device has a plurality of marker attachment points that receive fiducial markers and at least two of the marker attachment points of the marker attachment device are configured to receive fiducial markers in different orientations with respect to the marker attachment device and each other, as recited in claim 1.

None of the references discussed below disclose or suggest an open-ended frame having first and second arms, wherein the open-ended frame is configured to be removably attached to the maxillary holding device, the first arm has at least one marker attachment point that receives fiducial markers, the second arm has a plurality of marker attachment points that receive fiducial markers, and at least two of the marker attachment points of the second arm are configured to receive fiducial markers in different orientations with respect to the open-ended frame and each other, as recited in claim 6.

None of the references discussed below disclose or suggest an open-ended frame having first and second arms, wherein the open-ended frame is configured to be removably attached to the maxillary holding device, the first arm has at least one marker attachment point that receives

fiducial markers, the second arm has a plurality of marker attachment points that receive fiducial markers, and at least two of the marker attachment points of the second arm are configured to receive fiducial markers in different orientations with respect to the open-ended frame and each other, as recited in claim 14.

None of the references discussed below disclose or suggest a method of performing image-guided surgery on a patient including, among other things, attaching the open-ended frame with the plurality of fiducial markers to a patient using the maxillary holding device; calculating the position of any point in or on the patient relative to the frame; calibrating the frame and the reference emitter, while the patient is being prepared for surgery, so that the position of the frame relative to the reference emitter is determined; calculating the position of the frame relative to the reference emitter; removing the frame with the plurality of fiducial markers from maxillary holding device; attaching the maxillary holding device with the reference emitter to the patient; calculating the position of any point in the intraoperative-imaged patient anatomy relative to the reference emitter; tracking the reference emitter and the surgical probe/instrument simultaneously; calculating the position of the surgical probe/instrument relative to the patient's anatomy; and using the image-guided surgical system to guide surgery, as recited in claim 18.

None of the references discussed below disclose or suggest a method of calibrating an image-guided surgical system including, among other things, attaching the open-ended frame with the plurality of fiducial markers to a patient using the maxillary holding device; attaching the reference emitter to either the open-ended frame or the maxillary holding device; tracking the reference emitter and the surgical probe/instrument simultaneously and continuously calculating the position of the surgical probe/instrument relative to the reference emitter; and calibrating the image-guided surgical system with respect to the frame and the reference emitter by touching the surgical probe/instrument to each fiducial marker, so that the position of the frame relative to the reference emitter is determined and stored in the memory of the image-guided surgical system, as recited in claim 19.

The independent claims highlighted above are repeated below for the Examiner's convenience. The features highlighted above which are not disclosed or suggested in any of the references is underlined.

1. A fiducial marker holder apparatus for image-guided surgery comprising:

an open-ended frame having first and second arms, the open-ended frame being configured to be removably attached to a maxillary holding device and the first arm having at least one marker attachment point that receives fiducial markers; and

a marker attachment device disposed at a distal end of the second arm of the open-ended frame, the marker attachment device having a plurality of marker attachment points that receive fiducial markers, at least two of the marker attachment points of the marker attachment device being configured to receive fiducial markers in different orientations with respect to the marker attachment device and each other.

6. A fiducial marker holder apparatus for image-guided surgery comprising:

a maxillary holding device configured to be temporarily secured to only a maxillary-region of a patient;

an open-ended frame having first and second arms, the open-ended frame being configured to be removably attached to the maxillary holding device, the first arm having at least one marker attachment point that receives fiducial markers and the second arm having a plurality of marker attachment points that receive fiducial markers, at least two of the marker attachment points of the second arm being configured to receive fiducial markers in different orientations with respect to the open-ended frame and each other.

14. A fiducial marker holder system for image-guided surgery comprising:

a maxillary holding device having a first clamping part, a second clamping part and a fixing tool, the fixing tool being

configured to temporarily secure the first and second clamping parts to only a maxillary-region of a patient;

an open-ended frame having first and second arms, the open-ended frame being configured to be removably attached to the maxillary holding device, the first arm having at least one marker attachment point that receives fiducial markers and the second arm having a plurality of marker attachment points that receive fiducial markers, at least two of the marker attachment points of the second arm being configured to receive fiducial markers in different orientations with respect to the open-ended frame and each other; and

a reference emitter configured to be removably attached to the maxillary holding device or the open-ended frame.

18. A method of performing image-guided surgery on a patient using a maxillary holding device, an open-ended frame, a plurality of fiducial markers, a reference emitter, a surgical probe/instrument and an image-guided surgical system having a tracking sensor, the method comprising:

(a) attaching the open-ended frame with the plurality of fiducial markers to a patient using the maxillary holding device;

(b) acquiring a preoperative scan of the patient and the open-ended frame with the plurality of fiducial markers;

(c) removing the maxillary holding device from the patient;

(d) making a surgical plan, by the surgeon, from the preoperative scan;

(e) calculating the position of any point in or on the patient relative to the frame;

(f) attaching the reference emitter to the frame;

(g) activating the tracking sensor which then begins tracking the reference emitter and the frame;

(h) calibrating the frame and the reference emitter, while the patient is being prepared for surgery, so that the position of the frame relative to the reference emitter is determined;

(i) calculating the position of the frame relative to the reference emitter;

(j) removing the frame with the plurality of fiducial markers from maxillary holding device;

(k) attaching the maxillary holding device with the reference emitter to the patient;

(l) calculating the position of any point in the intraoperative-imaged patient anatomy relative to the reference emitter;

(m) activating a surgical probe/instrument;

(n) tracking the reference emitter and the surgical probe/instrument simultaneously;

(o) calculating the position of the surgical probe/instrument relative to the patient's anatomy; and

(p) using the image-guided surgical system to guide surgery.

19. A method of calibrating an image-guided surgical system that is used to perform image-guided surgery on a patient using a maxillary holding device, an open-ended frame, a plurality of fiducial markers, a reference emitter, a surgical probe/instrument and the image-guided surgical system having memory and a tracking sensor, the method comprising:

(a) attaching the open-ended frame with the plurality of fiducial markers to a patient using the maxillary holding device;

(b) acquiring a preoperative scan of the patient and the open-ended frame with the plurality of fiducial markers;

(c) removing the maxillary holding device from the patient;

(d) attaching the reference emitter to either the open-ended frame or the maxillary holding device;

(e) activating the tracking sensor which then begins tracking the reference emitter;

(f) activating the surgical probe/instrument;

(g) tracking the reference emitter and the surgical probe/instrument simultaneously and continuously calculating the

position of the surgical probe/instrument relative to the reference emitter; and

(h) calibrating the image-guided surgical system with respect to the frame and the reference emitter by touching the surgical probe/instrument to each fiducial marker, so that the position of the frame relative to the reference emitter is determined and stored in the memory of the image-guided surgical system.

Dependent claims 2-5, 7-13 and 15-17 incorporate the elements and steps of their respective independent claims, and thus are deemed patentable over the prior art of record.

Reference Cited in Search Report

U.S. Patent Application No. 6,096,048 (Howard '048) discloses a "frameless" stereotaxis skull fiducial marker system that uses custom-formed mouthpieces (i.e., bite blocks) fitted to maxillary teeth. A relatively thick medial portion of a tapered U-shaped bar is attached to a forward projecting connector on the mouthpiece. Thin distal ends of the rigid U-shaped bar support fiducial markers. The customized mouthpiece is stored for repeated use on a patient. As shown in Figs. 1-3, the fiducial markers are disposed in a linear array along the wings of the U-shaped bar. All of the fiducial markers on a wing are arranged in the same orientation relative to the wing and to each other, namely, normal to the bar, extending outwardly with respect to the patient's skull (Figs. 1-3). Howard '048 touts the simplified design of a detachable mouthpiece and U-shaped bar as being the reason why the device can be frameless and non-invasive (see column 2, line 50 – column 3, line 45).

Howard '048 fails to disclose or suggest a marker attachment device or a second arm of an open-ended frame (i.e., one wing of Howard '048) having at least two marker attachment points that are configured to receive fiducial markers in different orientations with respect to the marker attachment device and each other (e.g., normal and planar relative to the attachment device and/or second arm).

While Howard '048 mentions using the U-shaped bar and mouthpiece on a patient during a scan, such as an magnetic resonant imaging (MRI), Computerized Tomography (CT scan), and positron emission tomographic (PET) (column 6, lines 1-8), Howard '048 fails to disclose or suggest using such a marker attachment device to calibrate an image guided surgical system, especially for navigation *without* the marker holder. For example, at column 4, lines 5-6, Howard '048 notes that "[a]t the time of surgery, the bar is assembled on the mouthpiece which is placed back into the patient's mouth." Thus, the U-shaped bar of Howard '048 was intended to be used during a scan and during a surgical procedure.

Accordingly, Howard '048 teaches a simplified marker holder system for use during scanning and/or surgery that attaches to a mouthpiece instead of a frame, but fails to suggest any of the improvements claimed in the present invention such as concentrating fiducial markers in

different orientations with respect to one another and the frame and using such fiducial markers to calibrate an image guided surgical system operated without the markers.

Other References Known by Applicants

U.S. Patent Application No. 4,991,579 ("Allen," hereinafter, "Allen '579") discloses an invasive fiducial implant system for the human body that is detectable by an imaging system. The implants are physically tapped or screwed into a rigid portion of a human body such as the skull to be detected during a scanning process. Allen '579 discloses locating such invasive fiducials. Accordingly, Allen '579 fails to disclose or suggest an open-ended frame fiducial marker holder having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,142,930 ("Allen *et al.*," hereinafter, "Allen '930") discloses an interactive system for guiding the use of a surgical tool using an imaging technique such as CT scanning. Allen '930 is also based upon invasive fiducial markers which rigidly apply to the human body as well as an image guided surgical system including a multi-degree of freedom robotic arm. Allen '930 includes details of mapping image data and registration data for use during the image guided robotic procedure. However, Allen '930 fails to disclose or suggest an open-ended frame fiducial marker holder having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,230,338 ("Allen *et al.*," hereinafter, "Allen '338") discloses an interactive image guided surgical system related to Allen '930 also based upon invasive fiducial markers physically tapped into the human body and an image guided multi-degree of freedom robotic arm. For similar reasons, Allen '338 fails to disclose or suggest an open-ended frame fiducial marker holder having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,394,875 ("Lewis *et al.*," hereinafter, "Lewis '875") discloses an automatic ultrasonic localization system for targets implanted in a portion of a human anatomy. The system uses reflected radio frequency (RF) ultrasound signals to detect position of such an implanted object and to compute the depth of the object from the transducer. Accordingly, Lewis '875 fails to disclose or suggest an open-ended frame fiducial marker holder having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,551,429 ("Fitzpatrick *et al.*," hereinafter, "Fitzpatrick '429") discloses a method for determining the location of the center of an imageable portion of a fiducial marker using a marker having a detachable cap. The marker can be used in two configurations (i) the cap having a concave depression or divot to receive a spherical ball of an optical pen and (ii) with the marker having a localization cap detectable during an image scan (e.g., CT, MRI, PET, and the like). The reconfigurable localization cap permits markers to be located on a temporary or permanent frame and calibrated prior to scanning using an optical ball tip pen and then in the same orientation have the localization (detection) cap installed for use during scanning. Such caps disclosed in Fitzpatrick '429 can be utilized in conjunction with the present invention. However, Fitzpatrick '429 fails to disclose or suggest an open-ended frame fiducial marker holder having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,588,430 ("Bova *et al.*," hereinafter, "Bova '430") discloses a repeat fixation frameless stereo tactic guidance system relying on a bite plate having a plurality of light emitting diodes (LEDs) for detection by a multi-lens camera system. The bite plate is intended to be reattached to the teeth of a patient and used to determine position relative to the camera detected LED markers. Fig. 3 shows that the LED markers 48 are disposed in a linear array forward of the patient's maxillar teeth. The bite plate having LEDs of Bova '430 may be similar to a reference emitter that is removably attachable to a holding device. However, Bova '430 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to

one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,676,673 ("Ferre *et al.*," hereinafter, "Ferre '673") discloses a position tracking and imaging system for use during surgical procedures including a headset with two ear mounts and a nose bridge that spans from one ear across a patient's nose to the other ear. As noted, the primary objective of the headset is to provide a reference unit that may be easily attached to and removed from a patient's head wherein the headset may be repeatedly reattached in exactly the same place with a high degree of accuracy. The headset is used in combination with skin-mounted fiducial markers. In one embodiment (Fig. 18), the headset includes a plate that has fiducial balls disposed thereon all mounted in the same orientation (i.e., perpendicular to the plate). Accordingly, Ferre '673 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,803,089 ("Ferre *et al.*," hereinafter, "Ferre '089") is related to Ferre '673 and similarly discloses a position tracking and imaging system for use during surgical procedures including a headset. For similar reasons, Ferre '089 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,829,444 ("Ferre *et al.*," hereinafter, "Ferre '444") is related to Ferre '673 and similarly discloses a position tracking and imaging system for use during surgical procedures including a headset. For similar reasons, Ferre '444 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,873,822 ("Ferre *et al.*," hereinafter, "Ferre '822") is related to Ferre '673 and similarly discloses a position tracking and imaging system for use during surgical procedures including a headset. For similar reasons, Ferre '822 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,916,164 ("Fitzpatrick *et al.*," hereinafter, "Fitzpatrick '164") is related to Fitzpatrick '429 and similarly discloses a fiducial marker assembly comprising an imaging marker (Fig. 1A) and a base (Fig. 3A). The base includes a detachable cap for determining the location of a center of the imageable portion of the imaging marker (i.e., registration). Fitzpatrick '164 suggests that the markers be invasively, rigidly mounted to holes in a human skull during neurosurgery. However, such markers can be used with the fiducial marker holder and calibration system of the present invention. But, Fitzpatrick '164 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,954,647 ("Bova *et al.*," hereinafter, "Bova '647") is related to Bova '430 and similarly discloses a repeat fixation frameless stereo tactic guidance system relying on a bite plate having a plurality of light emitting diodes (LEDs) for detection by a multi-lens camera system. For similar reasons, Bova '647 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 5,967,980 ("Ferre *et al.*," hereinafter, "Ferre '980") is related to Ferre '673 and similarly discloses a position tracking and imaging system for use during surgical procedures including a headset. For similar reasons, Ferre '980 fails to disclose or

suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 6,106,464 ("Bass *et al.*," hereinafter, "Bass") discloses an A-mode ultrasound transducer is tracked in three-dimensions by an optical position tracking system as the transducer is scanned over the skin to generate measurements of bone surface distance from the transducer. The probe is optically tracked and position is correlated in the scan by a computer to create a composite display. Bass fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 6,080,164 ("Oshio *et al.*," hereinafter, "Oshio") discloses a stereotactic device for use with an imager (e.g., MR, PET, CT, etc.) which permits an imaging scan to be taken with reference to a personal coordinate system (or PCS) that is independent of a machine coordinate system (or MCS). The device is, similar to Ferre '673, a headset with two ear mounts and a nose bridge that spans from one ear across a patient's nose to the other ear. The Oshio also discloses methods using the device to obtain imaging scans are described such that the imaging scans are superimposable even if taken at different time periods using the same or a different imager. The device includes reference emitters ("localizing arrays") mounted on the bridge and each earpiece. Oshio fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 6,175,756 ("Ferre *et al.*," hereinafter, "Ferre '756") is related to Ferre '673 and similarly discloses a position tracking and imaging system for use during surgical procedures including a headset. For similar reasons, Ferre '756 fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame

and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 6,333,971 ("McCrory *et al.*," hereinafter, "McCrory") discloses an implantable fiducial marker having a sealed cavity for the introduction of an imaging agent that provides imaging capability in several modes, such as CT, MR, and the like. The disclosed marker may be invasively and fixedly attached, or it may be temporary and readily detachable from its anchor site. Such markers can be used with the fiducial marker holder and calibration system of the present invention. But, McCrory fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

U.S. Patent Application No. 6,584,339 ("Galloway, Jr., *et al.* ," hereinafter, "Galloway") discloses a method and apparatus for collecting and processing physical space data used while performing image-guided surgery is disclosed. Physical space data is collected by probing physical surface points of surgically exposed tissue. The physical space data provides three-dimensional (3D) coordinates for each of the physical surface points. Based on the physical space data collected, point-based registrations used to indicate surgical position in both image space and physical space are determined. The registrations are used to map into image space, image data describing the physical space of an ablative instrument used to perform the image-guided surgery, an ablation zone of the instrument, the surgically exposed tissue, and a particular portion of the tissue to be resected or ablated. The Galloway apparatus can be modified to be used in conjunction with the open-ended frame of the present invention to register location data of fiducial markers and/or to track the reference emitter in image guided procedures. However, Galloway fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

International Patent Application No. WO 97/06744 ("Brigham & Women's Hospital," hereinafter, "Brigham") is related to Oshio and similarly discloses stereotactic headset device for use with an imager. For similar reasons to Oshio, Brigham fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

International Patent Application No. WO 01/33511 A3 ("Case Western Reserve University," hereinafter, "Case") discloses a method of creating a 3D model of hard tissue within a human using a frameless approach to create fiduciary distances to position fiducial markers fixedly mounted to the human patient (Fig. 1). Accordingly, Case fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

International Patent Application No. WO 02/22015 A2 ("John Hopkins University School of Medicine," hereinafter, "John Hopkins") discloses an image registration system for creating a 3D model of a patient that uses a scanner (e.g., CT, MR, and the like) and a fiducial object places separate from the patent but in association with a medical instrument. The preferred fiducial object for use with CT imagers is one or more aluminum rods. John Hopkins fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

The article "Present state and Future perspectives of computer aided surgery in the field of ENT and skull base," by Caversaccio, *et al.* (hereinafter, "Caversaccio") discloses a plurality of computer-aided-surgery (CAS) devices including an optically-tracked A-mode ultrasonic probe, an optically-tracked drill, an optically-tracked laser, a microscope, and the like. Caversaccio describes a frameless optoelectronic system used to track such devices in image-

guided surgery and describes a dynamic reference base attached to a patients maxillary jaw. The reference base has four IREDs to track skull position during a procedure (page 52, column 2). Caversaccio also suggests using electromagnetic tracking systems using radio frequency electromagnetic sensors and electromechanical tracking systems using a mechanical linkage between the instrument and a (tracking) mechanical arm. However, Caversaccio fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

The article "Development of the First Force-Controlled Robot for Otoneurosurgery" by Federspil, *et al.* (hereinafter, "Federspil") discloses a force-controlled robotic arm for use during surgery. Federspil suggests that an improved arm may be combined with ultrasound-guided local navigation and/or infrared (optical)-guided global navigation. But, Federspil fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

The article "A noninvasive, reattachable skull fiducial marker system" by Howard, III, *et al.* (hereinafter, "Howard article") is by the patentees of Howard '048 (and one other) and similarly discloses a "frameless" stereotaxis skull fiducial marker system that uses custom-formed mouthpieces (i.e., bite blocks) fitted to maxillary teeth. The Howard article shows pictures of what appears to be more of a prototype version of the device shown in Howard '048, but still shows the fiducial markers on each wing mounted in the same orientation with respect to one another and the frame. Accordingly, the Howard article fails to disclose or suggest an open-ended frame fiducial marker holding device having marker attachment points configured to receive markers in different orientations with respect to one another and the frame and a method of calibrating an image guided surgical system using such an open-ended frame fiducial marker holder.

6. **Fee**

The fee required by 37 C.F.R. 1.17(i) is to be paid by the enclosed check for **$130.00**.

Please charge any fee deficiency to Deposit Account No. 50-1017.

Respectfully submitted,

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(Date)

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